

# **EXHIBIT C**

# DEXCOM INC

## FORM 10-Q (Quarterly Report)

Filed 8/2/2005 For Period Ending 6/30/2005

Address	5555 OBERLIN DRIVE SAN DIEGO, California 92121
Telephone	858-200-0200
CIK	0001093557

Powered By **EDGAR**  
Online®

<http://www.edgar-online.com/>

© Copyright 2005. All Rights Reserved.

Distribution and use of this document restricted under EDGAR Online's Terms of Use.

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549  
FORM 10 - Q

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2005

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission file number 000-51222

**DEXCOM, INC.**

(Exact name of Registrant as specified in its charter)

**Delaware**  
(State or Other Jurisdiction of  
Incorporation or Organization)

**33-0857544**  
(I.R.S. Employer  
Identification No.)

**555 Oberlin Drive**  
**San Diego, California**  
(Address of Principal Executive offices)

**92121**  
(Zip Code)

Registrant's Telephone Number, including area code: (858) 200-0200

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes  No

Indicate by check mark whether the Registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

As of July 15, 2005, 25,371,413 shares of the Registrant's common stock were outstanding.

**DexCom, Inc.**  
**Table of Contents**

**PART I FINANCIAL INFORMATION****ITEM 1. Financial Statements**

Balance Sheets as of June 30, 2005 (unaudited) and December 31, 2004.

Statements of Operations (unaudited) for the three and six months ended June 30, 2005 and 2004, and for the period from May 13, 1999 (inception) through June 30, 2005

Statements of Cash Flows (unaudited) for the three and six months ended June 30, 2005 and 2004, and for the period from May 13, 1999 (inception) through June 30, 2005

Notes to Financial Statements (unaudited)

**ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations****ITEM 3. Quantitative and Qualitative Disclosures about Market Risk****ITEM 4. Controls and Procedures****PART II OTHER INFORMATION****ITEM 1. Legal Proceedings****ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds****ITEM 3. Defaults Upon Senior Securities****ITEM 4. Submission of Matters to a Vote of Security Holders****ITEM 5. Other Information****ITEM 6. Exhibits****SIGNATURES**

**DexCom, Inc.**  
**(a development stage company)**  
**BALANCE SHEETS**

	June 30, 2005 (unaudited)	December 31, 2004
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 51,490,448	\$ 27,229,208
Short-term marketable securities, available-for-sale	15,094,016	—
Prepaid and other current assets	760,046	43,781
Total current assets	<u>67,344,510</u>	<u>27,272,989</u>
Property and equipment, net	2,482,089	1,851,892
Restricted cash	250,000	200,000
Deferred offering costs and other assets	—	33,000
Total assets	<u>\$ 70,076,599</u>	<u>\$ 29,357,881</u>
<b>Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)</b>		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 2,136,014	\$ 1,018,879
Accrued payroll and related expenses	461,638	328,476
Accrued clinical trials	270,915	220,875
Total current liabilities	<u>2,868,567</u>	<u>1,568,230</u>
Deferred rent	146,865	125,241
Commitments and contingencies		
Redeemable convertible Series B preferred stock, \$0.001 par value, no shares and 11,304,114 shares authorized, issued and outstanding at June 30, 2005 and December 31, 2004, respectively.	—	20,878,086
Redeemable convertible Series C preferred stock, \$0.001 par value, no shares and 13,043,478 shares authorized; no shares and 12,790,870 shares issued and outstanding at June 30, 2005 and December 31, 2004, respectively.	—	34,740,360
Redeemable convertible Series D preferred stock, \$0.001 par value, no shares and 8,700,000 shares authorized; no shares and 8,355,886 shares issued and outstanding at June 30, 2005 and December 31, 2004, respectively.	—	21,355,894
Stockholders' equity (deficit):		
Convertible Series A preferred stock, \$0.001 par value, no shares and 3,000,000 shares authorized; no shares and 3,000,000 issued and outstanding at June 30, 2005 and December 31, 2004, respectively.	—	3,000
Preferred stock, \$0.001 par value, 5,000,000 authorized; no shares issued and outstanding at June 30, 2005.	—	—
Common stock, \$0.001 par value, 100,000,000 and 50,000,000 authorized; 25,371,413 and 2,323,300 shares issued and outstanding at June 30, 2005 and December 31, 2004, respectively.	25,371	2,323
Additional paid-in capital	134,191,155	6,218,012
Deferred stock-based compensation	(1,756,559)	(2,648,336)
Deficit accumulated during the development stage	(65,377,344)	(52,884,929)
Accumulated and other comprehensive income (loss)	(21,456)	—
Total stockholders' equity (deficit)	<u>67,061,167</u>	<u>(49,309,930)</u>
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	<u>\$ 70,076,599</u>	<u>\$ 29,357,881</u>

See accompanying notes to financial statements

**DexCom, Inc.**  
**(a development stage company)**  
**STATEMENTS OF OPERATIONS**  
**(unaudited)**

					Period from May 13, 1999 (inception) through June 30, 2005	
	Three Months Ended June 30,		Six Months Ended June 30,			
	2005	2004	2005	2004		
<b>Costs and expenses:</b>						
Research and development	\$ 4,978,718	\$ 2,802,892	\$ 9,982,995	\$ 5,636,993	\$ 46,095,729	
Selling, general and administrative	1,382,934	353,213	1,914,609	668,964	9,504,928	
Stock-based compensation:						
Research and development	366,850	18,849	797,650	37,530	1,088,764	
Selling, general and administrative	113,724	24,360	268,644	52,331	426,219	
Total costs and expenses	6,842,226	3,199,314	12,963,898	6,395,818	57,115,640	
Interest and other income	457,978	33,068	593,715	73,452	1,999,065	
Net loss	(6,384,248)	(3,166,246)	(12,370,183)	(6,322,366)	(55,116,575)	
Accretion to redemption value of Series B, Series C, and Series D redeemable convertible preferred stock						
	(15,242)	(808,628)	(122,232)	(1,617,256)	(10,260,769)	
Net loss attributable to common stockholders	\$ (6,399,490)	\$ (3,974,874)	\$ (12,492,415)	\$ (7,939,622)	\$ (65,377,344)	
Basic and diluted net loss per share attributable to common stockholders	\$ (0.29)	\$ (1.75)	\$ (1.01)	\$ (3.51)		
Shares used to compute basic and diluted net loss per share attributable to common stockholders	22,140,149	2,265,985	12,417,909	2,260,645		

See accompanying notes to financial statements

**DexCom, Inc.**  
**(a development stage company)**  
**STATEMENTS OF CASH FLOW**  
**(unaudited)**

	Six Months Ended June 30,		Period from May 13, 1999 (inception) through June 30,
	2005	2004	2005
<b>Operating activities</b>			
Net loss	\$ (12,370,183)	\$ (6,322,366)	\$ (55,116,575)
Adjustments to reconcile net loss to cash used in operating activities:			
Depreciation and amortization	340,306	177,272	1,802,458
Amortization of stock-based compensation	1,003,478	89,861	1,452,167
Accretion and amortization related to investments, net	(4,467)	—	(4,467)
Interest on converted notes	—	—	70,480
Loss on disposal of equipment	—	—	65,767
Compensation expense associated with stock options issued to consultants	62,816	—	101,863
Changes in operating assets and liabilities:			
Prepaid and other assets	(601,536)	22,630	(678,317)
Restricted cash	(50,000)	(200,000)	(250,000)
Accounts payable and accrued liabilities	1,167,175	593,673	2,406,929
Accrued payroll and related expenses	133,162	257,170	461,638
Deferred rent	21,624	108,672	146,865
Net cash used in operating activities	<u>(10,297,625)</u>	<u>(5,273,088)</u>	<u>(49,541,192)</u>
<b>Investing activities</b>			
Purchase of available-for-sale marketable securities	(15,225,734)	—	(22,991,014)
Proceeds from the maturity of available-for-sale marketable securities	—	—	7,765,280
Purchase of property and equipment	(970,503)	(1,207,827)	(4,332,031)
Proceeds on sale of equipment	—	—	1,017
Net cash used in investing activities	<u>(16,196,237)</u>	<u>(1,207,827)</u>	<u>(19,556,748)</u>
<b>Financing activities</b>			
Proceeds from convertible notes payable	—	—	2,000,000
Proceeds from issuance of common stock	50,755,102	2,765	50,888,721
Net proceeds from issuance of preferred stock	—	—	67,699,667
Net cash provided by financing activities	<u>50,755,102</u>	<u>2,765</u>	<u>120,588,388</u>
Increase (decrease) in cash and cash equivalents	24,261,240	(6,478,150)	51,490,448
Cash and cash equivalents, beginning of period	27,229,208	20,016,186	—
Cash and cash equivalents, ending of period	<u>\$ 51,490,448</u>	<u>\$ 13,538,036</u>	<u>\$ 51,490,448</u>
<b>Non-cash investing and financing transactions:</b>			
Purchase of technology in exchange for common stock	\$ —	\$ —	\$ 19,000
Conversion of notes payable into Series B preferred stock	\$ —	\$ —	\$ 2,000,000
Conversion of Series A, B, C, and D preferred stock	<u>\$ 77,099,572</u>	<u>\$ —</u>	<u>\$ 77,099,572</u>
Accretion to redemption value of Series B, Series C, and Series D redeemable convertible preferred stock	\$ 122,232	\$ 1,617,256	\$ 10,260,769
Unrealized loss on marketable securities	<u>\$ 21,456</u>	<u>\$ —</u>	<u>\$ 21,456</u>

See accompanying notes to financial statements

**DexCom, Inc.**  
**(a development stage company)**  
**NOTES TO FINANCIAL STATEMENTS**  
**( Unaudited)**

## **1. Organization and Summary of Significant Accounting Policies**

### ***Organization and Basis of Presentation***

DexCom, Inc. (the “Company”) is a development stage medical device company focused on the design and development of continuous glucose monitoring systems for people with diabetes. Since inception the Company has devoted substantially all of its resources to start-up activities, raising capital and research and development, including product design, testing, manufacturing and clinical trials. The Company has focused its development activities on two continuous glucose monitoring systems: a short-term system with a sensor that can be inserted by a patient, and a long-term system with a sensor that can be implanted by a physician. The Company’s glucose monitoring systems are designed to provide real-time continuous blood glucose values, trend data and alerts to assist patients in managing their blood glucose levels. The Company has not generated any revenue from its development activities and will not be able to generate revenue until one of its products is approved, if ever.

The information contained herein has been prepared in accordance with instructions for Form 10-Q and Rule 10-01 of Regulation S-X. The information as of June 30, 2005, for the three and six months ended June 30, 2004 and 2005, and for the period from May 13, 1999 (inception) through June 30, 2005 is unaudited. In the opinion of management, the accompanying unaudited financial statements contain all adjustments (consisting only of normal and recurring accruals) necessary to present fairly the financial position of the Company as of June 30, 2005, and the results of its operations and cash flows for the six months ended June 30, 2004 and 2005, and for the period from May 13, 1999 (inception) through June 30, 2005. These results have been determined on the basis of accounting principles generally accepted in the United States of America and applied consistently with those used in the preparation of the audited financial statements for the year ended December 31, 2004 included in the Prospectus filed by the Company pursuant to Rule 424(b) under the Securities Act of 1933, as amended (the “Securities Act”), with the Securities and Exchange Commission on April 13, 2005.

Certain information and footnote disclosures normally included in financial statements presented in accordance with accounting principles generally accepted in the United States of America have been omitted in accordance with the applicable rules to Form 10-Q. The accompanying financial statements should be read in conjunction with our audited financial statements and notes thereto for the year ended December 31, 2004 included in the Prospectus filed by the Company with the Securities and Exchange Commission on April 13, 2005.

### ***Use of Estimates***

The preparation of financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from these estimates. Significant estimates include estimated clinical study expenses that are comprised of payments for work performed by contract research organizations, physicians and participating hospitals. Expenses are accrued for clinical studies performed by contract research organizations based on estimates of work performed under contracts. Expenses for setting up clinical trial sites are accrued immediately. Clinical expenses related to patient enrollment and monitoring are accrued as patients are enrolled and monitored in a trial.

### ***Stock-Based Compensation***

The Company accounts for employee stock options using the intrinsic-value method in accordance with Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees*, Financial Accounting Standards Board, or FASB, Interpretation, or FIN No. 44, *Accounting for Certain Transactions Involving Stock Compensation, an Interpretation of APB No. 25*, and related interpretations and has adopted the disclosure-only provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*.

Options or stock awards issued to non-employees are recorded at their fair value as determined in accordance with SFAS No. 123 and Emerging Issues Task Force No. 96-18, *Accounting for Equity Instruments that are Issued to Other than Employees for Acquiring, or in Conjunction with Selling Goods and Services* and recognized over the related service period.

The information regarding net loss as required by SFAS No. 123, as amended, has been determined as if the Company had accounted for its employee stock options under the fair-value method. The resulting effect on net loss pursuant to SFAS No. 123 is not likely to be representative of the effects on net loss pursuant to SFAS No. 123 in future periods, since future periods are likely to include additional grants and the irregular impact of future years’ vesting.

The table below illustrates the effect on net loss and net loss per share attributable to common stockholders had the Company applied the fair value provisions of SFAS No. 123 to employee stock compensation.

	Three Months Ended June 30,		Six Months Ended June 30,		Period from May 13, 1999 (inception) through June 30, 2005
	2005	2004	2005	2004	
Net loss attributable to common stockholders, as reported	\$ (6,399,490)	\$ (3,974,874)	\$ (12,492,415)	\$ (7,939,622)	\$ (65,377,344)
Add: Stock-based compensation expense included in net loss	480,574	43,209	1,066,294	89,861	1,514,983
Deduct: Stock-based compensation expense determined under fair-value method	(1,177,144)	(71,126)	(1,987,746)	(132,617)	(2,689,828)
Pro forma net loss attributable to common stockholders	\$ (7,096,060)	\$ (4,002,791)	\$ (13,413,867)	\$ (7,982,378)	\$ (66,552,189)
Basic and diluted net loss per share attributable to common Stockholders, as reported	\$ (0.29)	\$ (1.75)	\$ (1.01)	\$ (3.51)	
Pro forma basic and diluted net loss per share attributable to common stockholders	\$ (0.32)	\$ (1.77)	\$ (1.08)	\$ (3.53)	

## 2. Comprehensive Loss

SFAS No. 130, *Reporting Comprehensive Income*, requires that all components of comprehensive income, including net income, be reported in the financial statements in the period in which they are recognized. Comprehensive income is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Net income and other comprehensive income, including foreign currency translation adjustments, and unrealized gains and losses on investments, shall be reported, net of their related tax effect, to arrive at comprehensive income. The Company's comprehensive loss is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,		Period from May 13, 1999 (inception) through June 30, 2005
	2005	2004	2005	2004	
Net loss attributable to common stockholders	\$ (6,399,490)	\$ (3,974,874)	\$ (12,492,415)	\$ (7,939,622)	\$ (65,377,344)
Unrealized loss on available-for-sale marketable securities	(12,822)	—	(21,456)	—	(21,456)
Comprehensive loss	\$ (6,412,312)	\$ (3,974,874)	\$ (12,513,871)	\$ (7,939,622)	\$ (65,398,800)

## 3. Net Loss Per Common Share

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. For purposes of this calculation, redeemable convertible preferred stock, convertible preferred stock, stock options and the outstanding warrant are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

Historical outstanding anti-dilutive securities not included in diluted net loss per share attributable to common stockholders calculation:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2005	2004	2005	2004
Redeemable convertible preferred stock	—	24,094,984	—	24,094,984
Convertible preferred stock	—	3,000,000	—	3,000,000
Warrant	43,729	—	43,729	—
Options to purchase common stock	3,114,075	2,509,050	3,114,075	2,509,050
Restricted stock	19,750	—	19,750	—
	<u>3,177,554</u>	<u>29,604,034</u>	<u>3,177,554</u>	<u>29,604,034</u>

#### **Pro Forma Net Loss per Share**

Management believes that the additional disclosure below is useful to investors because it shows what basic loss per share would have been if the conversions of the company's preferred stock had occurred at the beginning of the respective periods being reported rather than during the periods. The calculation of unaudited pro forma basic and diluted net loss per share attributable to common stockholders assumes the conversion of all shares of Series A convertible preferred stock, Series B, Series C and Series D redeemable convertible preferred stock into shares of common stock using the as-if-converted method, as if such conversion had occurred as of January 1, 2004, or the original issuance date, if later. The actual conversion date was April 13, 2005. The Company's pro forma net loss per share is as follows:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2005	2004	2005	2004
<b>Pro forma</b>				
Numerator:				
Net loss attributable to common stockholders, as reported	\$ (6,399,490)	\$ (3,974,874)	\$ (12,492,415)	\$ (7,939,622)
Reversal of accretion to redemption value of Series B, Series C and Series D redeemable convertible preferred stock	15,242	808,628	122,232	1,617,256
Pro forma net loss attributable to common stockholders	<u>\$ (6,384,248)</u>	<u>\$ (3,166,246)</u>	<u>\$ (12,370,183)</u>	<u>\$ (6,322,366)</u>
Denominator:				
Shares used to compute basic and diluted net loss per share attributable to common stockholders	22,140,149	2,265,985	12,417,909	2,260,645
Pro forma adjustments to reflect assumed weighted-average effect of conversion of preferred stock on January 1, 2005 and 2004	2,532,200	13,547,492	10,086,847	13,547,492
Pro forma shares used in basic and diluted pro forma net loss per share	<u>24,672,349</u>	<u>15,813,477</u>	<u>22,504,756</u>	<u>15,808,137</u>
Pro forma basic and diluted net loss per share attributable to common stockholders	\$ (0.26)	\$ (0.20)	\$ (0.55)	\$ (0.40)

#### **4. Stockholders' Equity (Deficit)**

##### *Stock Split*

On March 23, 2005, the Company effected a 1-for-2 reverse stock split of the outstanding common stock. The accompanying financial statements and these notes give retroactive effect to the reverse stock split for all periods presented.

##### *Initial Public Offering*

On April 19, 2005, the Company closed the initial public offering of its common stock in which it sold 4,700,000 shares of common stock for gross proceeds of \$56.4 million. After deduction of underwriting discounts and commissions, the Company received proceeds of \$52.5 million that excluded \$2.0 million in offering expenses payable by the Company.

##### *Changes in Capitalization*

Effective April 13, 2005, the Amended and Restated Certificate of Incorporation authorizes "blank check" preferred stock, which enables the Board of Directors to designate and issue, without stockholder approval, preferred stock with rights senior to those of common stock.

**Convertible Preferred Stock**

Effective April 13, 2005 and in conjunction with the Company's initial public offering, all 35,450,870 shares of preferred stock converted to 17,725,401 shares of common stock.

**5. Recent Accounting Pronouncements**

In December 2004 and as amended in April 2005, the FASB issued SFAS No. 123 (revised 2004), *Share-Based Payment*, or SFAS No. 123R, which replaces SFAS No. 123, and supercedes APB Opinion No. 25. SFAS No. 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values at the fiscal year beginning January 1, 2006, with early adoption encouraged. The pro forma disclosures previously permitted under SFAS No. 123 no longer will be an alternative to financial statement recognition. Under SFAS No. 123R, the Company must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at date of adoption. The transition methods include prospective and retroactive adoption options. Under the retroactive option, prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The prospective method requires that compensation expense be recorded for all unvested stock options and restricted stock at the beginning of the first quarter of adoption of SFAS No. 123R, while the retroactive methods would record compensation expense for all unvested stock options and restricted stock beginning in the first period restated. The Company is evaluating the requirements of SFAS No. 123R and expects that the adoption of SFAS No. 123R will have a material impact on the Company's results of operations and earnings per share. The Company has not yet determined the method of adoption or the effect of adopting SFAS No. 123R, and it has not determined whether the adoption will result in amounts that are similar to the current pro forma disclosures under SFAS No. 123.

**6. Benefit Plans**

The following plans became effective April 13, 2005, the effective date of the Company's registration statement on Form S-1 for its initial public offering:

- The 2005 Equity Incentive Plan - the 2005 Equity Incentive Plan replaces the 1999 equity incentive plan and includes a reserve of 3,000,000 shares of common stock. The shares reserved include all shares that are available under the 1999 plan on the day it is terminated.
- The 2005 Employee Stock Purchase Plan - the 2005 Employee Stock Purchase has a reserve of 150,000 shares of common stock.

**7. Related Party Transactions**

The Company's Chairman retains one-half ownership in Archipelago Aviation and is also a director of Oracle Corporation. During the six months ended June 30, 2005, the Company incurred costs with Archipelago Aviation totaling \$191,288 for airline transportation related to travel activities during the Company's initial public offering and subsequent clinical site visits. Expenses incurred relating to an Oracle ERP system for the six months ended June 30, 2005 and 2004 totaled \$22,174 and \$27,470, respectively. The Company believes that the aforementioned arrangements were at no less favorable rates to the Company than those that could have been obtained from unrelated third parties.

**8. Commitments and Contingencies***Lease*

In May 2005, the Company entered into a lease agreement for approximately 7,000 square feet in additional facilities space located adjacent to the Company's existing corporate office. Rental obligations under the lease agreement are as follows:

<b>Fiscal Year Ending</b>	
2005 (*)	\$ 41,548
2006	101,405
2007	104,362
2008	107,320
2009	110,700
2010	114,080
2011 (*)	48,238
<b>Total</b>	<b>\$ 627,653</b>

(\*) Excludes a \$50,000 security deposit payable by the Company in 2005 and refundable to the Company in 2011.

**ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS****CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This document, including the following Management's Discussion and Analysis of Financial Condition and Results of Operations, contains forward-looking statements that are based upon current expectations. These forward-looking statements fall within the meaning of the federal securities laws that relate to future events or our future financial performance. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "expect," "plan," "anticipate," "believe," "estimate," "intend," "potential" or "continue" or the negative of these terms or other comparable terminology. Forward-looking statements involve risks and uncertainties. Our actual results and the timing of events could differ materially from those anticipated in our forward-looking statements as a result of many factors, including whether we are able to introduce any products to the market or generate revenue, whether we receive FDA approval for our technologies, competition in our marketplace and the other risks those set forth below under "Factors That May Affect Our Financial Condition And Results Of Operations" and elsewhere in this report. We assume no obligation to update any of the forward-looking statements after the date of this report or to conform these forward-looking statements to actual results.

**Overview**

We are a development stage medical device company focused on the design and development of continuous glucose monitoring systems for people with diabetes. Since inception we have devoted substantially all of our resources to start-up activities, raising capital and research and development, including product design, testing, manufacturing and clinical trials. We have focused our development activities on two continuous glucose monitoring systems: a short-term system with a sensor that can be inserted by a patient and a long-term system with a sensor that can be implanted by a physician. Our glucose monitoring systems are designed to provide real-time continuous blood glucose values, trend data and alerts to assist patients in managing their blood glucose levels. We have not generated any revenue from our development activities and will not be able to generate revenue until one of our products is approved, if ever.

In March 2005, we filed an application for premarket approval, or PMA, for our short-term continuous glucose monitoring system, or STS, with the Food and Drug Administration, or FDA. Premarket approval is the FDA process of scientific and regulatory review to evaluate the safety and efficacy of medical devices like those we are developing. In May 2005 we received notification from the FDA that our PMA was accepted as filed and granted expedited review status. In July 2005, we completed our 100-day meeting with the FDA and expect to receive additional written requests for information to support the PMA filing of our short-term system. Additionally, we are conducting an 80-patient clinical trial for our second generation long-term system and intend to submit a PMA application after completion of the trial, if the data warrants submittal. Our clinical trials may be delayed due to scheduling issues with patients and investigators, institutional review boards, sensor performance and manufacturing supply constraints, among other factors. Support of these clinical trials requires significant resources in research and development, manufacturing, quality assurance, and clinical and regulatory personnel.

We are currently increasing our manufacturing capacity and personnel to enable us to produce commercial quantities of our devices. Due to the lead-time associated with increases in capacity, this expansion will be initiated prior to the approval, if received by the FDA, of our products. Our capacity expansion could be constrained by the lack of readily available laboratory and manufacturing space, material availability, equipment design, production and validation, regulatory approval of our factory personnel staffing and other factors. Prior to obtaining regulatory approval, we will also begin to hire sales and marketing personnel. If we obtain the necessary regulatory approvals, we plan to launch our products in the United States with our own direct sales force.

To date, we have not generated any revenue, and we have incurred net losses in each year since our inception in May 1999. Through June 30, 2005, we had a deficit accumulated during the development stage of \$65.4 million. We expect our losses to continue and increase as we expand our clinical trial activities and initiate commercialization activities. We have financed our operations primarily through private placements and an initial public offering (IPO) of equity securities. In April 2005, we completed our IPO in which we sold 4,700,000 shares of common stock for gross proceeds of \$56.4 million. After deduction of underwriting discounts and commissions, we received proceeds of \$52.5 million that excluded \$2.0 million in offering expenses payable by us.

**Financial Operations****Revenue**

To date, we have not generated any revenue from the sale of our continuous glucose monitoring systems. We do not expect to generate any revenue from our systems until at least 2006.

**Research and Development**

Our research and development expenses primarily consist of engineering and research expenses related to our continuous glucose monitoring technology, clinical trials, regulatory expenses and manufacturing expenses incurred to build our clinical trial glucose monitoring systems. These expenses are primarily related to employee compensation, including salary, fringe benefits, recruitment, relocation and temporary employee expenses. We also incur significant expenses to operate our clinical trials including trial design, clinical site reimbursement, data management and associated travel expenses. Our research and development expenses also include fees for outside design services, contractors and materials, and assembly expenses for our glucose monitoring systems. From our inception through June 30, 2005, we have incurred \$46.1 million in research and development expenses.

**Selling, General and Administrative**

Our selling, general and administrative expenses primarily consist of compensation for our executive, financial, marketing and administrative functions. Other significant expenses include trade show expenses, insurance, professional fees for our outside legal counsel and our independent auditors and expenses for board meetings. From our inception through June 30, 2005, we have incurred \$9.5 million for selling, general and administrative expenses.

**Stock-Based Compensation**

Stock-based compensation consists of compensation expense related to stock option programs. This compensation expense is reflected separately in our financial statements and is allocated among our research and development expenses and selling, general and administrative expenses. Stock-based employee compensation expense, which is a non-cash charge, results from employee stock option grants at exercise prices that, for financial reporting purposes, are deemed to be below the estimated fair value of the underlying common stock on the date of grant. Prior to our IPO in April 2005, our board of directors determined the estimated fair value of our common stock on the date of grant. Stock-based employee compensation equals the difference between the reassessed estimated fair value per share of our common stock on the date of grant and the exercise price per share and is amortized on an accelerated basis over the vesting period of the stock option. Additionally, stock-based compensation consists of options issued to non-employees that are recorded at their fair value. From inception through June 30, 2005, we have incurred \$1.5 million in stock-based compensation expense.

**Results of Operations****Comparison of the Three Months Ended June 30, 2005 and 2004**

**Research and Development.** Research and development expense, excluding stock based compensation, increased \$2.2 million to \$5.0 million for the three months ended June 30, 2005, compared to \$2.8 million for the three months ended June 30, 2004. The increase was primarily related to \$0.6 million for additional clinical trials of our glucose monitoring systems, \$0.6 million in compensation for additional employees, \$0.4 million in sensor design costs and \$0.3 million in materials to produce glucose monitoring systems for our clinical trials.

**Selling, General and Administrative.** Selling, general and administrative expense increased \$1.0 million to \$1.4 million for the three months ended June 30, 2005, compared to \$0.4 million for the three months ended June 30, 2004. The increase was primarily due to \$0.5 million for initial marketing expense and \$0.4 million related to expenses associated with operating as a public company including independent auditor and compliance expenses, insurance, legal fees and additional accounting personnel.

**Stock-Based Compensation.** In connection with the grant of stock options to employees, consultants and directors, amortized compensation expense increased \$438,000 to \$481,000 for the three months ended June 30, 2005 compared to \$43,000 for the three months ended June 30, 2004. The increase in amortized compensation expense, which is allocated between research and development and selling, general, and administrative, was due to the combination of additional option grants and higher estimated fair values per option grant for options granted subsequent to February 2004.

**Interest and Other Income.** Interest and other income increased \$425,000 to \$458,000 for the three months ended June 30, 2005, compared to \$33,000 for the three months ended June 30, 2004. The increase was due to higher combined average cash, cash equivalents, and short-term marketable securities balances due to our April 2005 IPO, along with higher interest rates.

**Comparison of the Six Months Ended June 30, 2005 and 2004**

**Research and Development.** Research and development expense, excluding stock based compensation, increased \$4.4 million to \$10.0 million for the six months ended June 30, 2005, compared to \$5.6 million for the six months ended June 30, 2004. The increase was primarily related to \$1.5 million for clinical trials of our glucose monitoring systems, \$1.3 million in compensation for additional employees and consultants, \$0.8 million to produce glucose monitoring systems for our clinical trials, and \$0.5 million in sensor design costs.

**Selling, General and Administrative.** Selling, general and administrative expense increased \$1.2 million to \$1.9 million for the six months ended June 30, 2005, compared to \$0.7 million for the six months ended June 30, 2004. The increase was due to \$0.5 million in initial marketing costs and \$0.6 million related to expenses associated with operating as a public company including independent auditor and compliance expenses, insurance, legal fees and additional accounting personnel.

**Stock-Based Compensation.** In connection with the grant of stock options to employees, consultants and directors, amortized compensation expense increased \$976,000 to \$1,066,000 for the six months ended June 30, 2005 compared to \$90,000 for the six months ended June 30, 2004. The increase in amortized compensation expense, which is allocated between research and development and selling, general, and administrative, was due to the combination of additional option grants and higher estimated fair values per option grant for options granted subsequent to February 2004.

**Interest and Other Income.** Interest and other income increased \$521,000 to \$594,000 for the six months ended June 30, 2005, compared to \$73,000 for the six months ended June 30, 2004. The increase was due to higher combined average cash, cash equivalents, and short-term marketable securities balances due to our April 2005 IPO along with higher interest rates.

### **Liquidity and Capital Resources**

We are in the development stage and have incurred losses since our inception in May 1999. As of June 30, 2005 we had a deficit accumulated during the development stage of \$65.4 million. We have funded our operations solely from the sale of equity securities, raising aggregate net proceeds of \$120.6 million through June 30, 2005. As of June 30, 2005, we had working capital of \$64.5 million, including \$66.6 million in cash, cash equivalents, and short-term marketable securities. On April 19, 2005, we completed our IPO in which we sold 4,700,000 shares of common stock for gross proceeds of \$56.4 million. After deduction of underwriting discounts and commissions, we received proceeds of \$52.5 million that excluded \$2.0 million in offering expenses payable by us. Concurrent with the closing of our IPO, all of our outstanding preferred stock converted into common stock.

Net cash used in operating activities increased \$5.0 million to \$10.3 million for the six months ended June 30, 2005, compared to \$5.3 million for the six months ended June 30, 2004. The increase in cash used in operations was primarily due to our net loss as we continued efforts to commercialize our products, partially offset by higher accounts payable and accrued liabilities, and amortization of stock-based compensation.

Net cash used in investing activities increased \$15.0 million to \$16.2 million for the six months ended June 30, 2005, compared to \$1.2 million for the six months ended June 30, 2004. The increase was primarily due to the purchases of short-term marketable securities.

Net cash provided by financing activities increased \$50.8 million to \$50.8 million for the six months ended June 30, 2005, compared to \$3,000 for the six months ended June 30, 2004. The increase was due to the net proceeds from our April 2005 IPO and the exercise of stock options.

### **Operating Capital and Capital Expenditure Requirements**

To date, we have not commercialized any products. We anticipate that we will continue to incur net losses for the next several years as we develop our products, expand our clinical development team and corporate infrastructure, and prepare for the potential commercial launch of our continuous glucose monitoring systems.

We do not expect to generate significant product revenue until we successfully obtain marketing approval for and begin selling our continuous glucose monitoring systems. We believe that the net proceeds from our IPO, together with our cash, cash equivalents, and short-term marketable securities balances, and the interest we earn on these balances, will be sufficient to meet our anticipated cash requirements with respect to clinical trials, PMA applications and any initial commercial launches of our long-term and short-term continuous glucose monitoring systems, and to meet our other anticipated cash needs for at least the next twelve months. If our available cash, cash equivalents and marketable securities are insufficient to satisfy our liquidity requirements, or if we develop additional products, we may seek to sell additional equity or debt securities or obtain a credit facility. The sale of additional equity and debt securities may result in additional dilution to our stockholders. If we raise additional funds through the issuance of debt securities or preferred stock, these securities could have rights senior to those of our common stock and could contain covenants that would restrict our operations. We may require additional capital beyond our currently forecasted amounts. Any such required additional capital may not be available on reasonable terms, if at all. If we are unable to obtain additional financing, we may be

required to reduce the scope of, delay or eliminate some or all of our planned research, development and commercialization activities, which could harm our business.

Because of the numerous risks and uncertainties associated with the development of continuous glucose monitoring technologies, such as our short-term and long-term systems, we are unable to estimate the exact amounts of capital outlays and operating expenditures associated with our current and anticipated clinical trials. Our future funding requirements will depend on many factors, including, but not limited to:

- the costs and timing of regulatory approval;
- our ability to scale our manufacturing operations;
- the rate of progress and cost of our clinical trials and other development activities;
- the success of our research and development efforts;
- the expenses we incur in developing, selling and marketing our products;
- the revenue generated by sales of our future products;
- the emergence of competing or complementary technological developments;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual product rights;
- the terms and timing of any collaborative, licensing and other arrangement that we may establish; and
- the acquisition of businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

### **Critical Accounting Policies and Estimates**

The discussion and analysis of our financial condition and results of operations are based on our financial statements, which we have prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported revenue and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 1 to our financial statements included elsewhere in this report and the prospectus from our initial public offering, we believe that the following accounting policies and estimates are most critical to a full understanding and evaluation of our reported financial results.

#### **Stock-Based Compensation**

We account for employee stock options using the intrinsic-value method in accordance with Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees*, Financial Accounting Standards Board, or FASB, Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation*, an interpretation of APB No. 25, and related interpretations. We have adopted the disclosure-only provisions of Statement of Financial Accounting Standards, or SFAS, No. 123, *Accounting for Stock-Based Compensation*, as amended.

The information regarding net loss as required by SFAS No. 123, presented in Note 1 to our financial statements, has been determined as if we had accounted for our employee stock options under the fair value method. The resulting effect on net loss pursuant to SFAS No. 123 is not likely to be representative of the effects on net loss pursuant to SFAS No. 123 in future years, since future years are likely to include additional grants and the irregular impact of future years' vesting.

Stock-based compensation expense, which is a non-cash charge, results from employee stock option grants at exercise prices that, for financial reporting purposes, are deemed to be below the estimated fair value of the underlying common stock on the date of grant. Given the absence of an active market for our common stock, our board of directors determined the estimated fair value of our common stock on the date of grant based on several factors, including progress and milestones achieved in our business, sales of

convertible preferred stock and valuation of existing comparable publicly-traded companies. Stock-based compensation expense per share equals the difference between the fair value per share of our common stock on the date of grant and the exercise price per share, and is amortized on an accelerated basis over the vesting period of the option, which is generally four years.

### **Clinical Trial Accounting**

We record accruals for estimated clinical study expenses, comprising payments for work performed by contract research organizations, physicians and participating hospitals. These expenses are a significant component of research and development expenses. We accrue expenses for clinical studies performed by contract research organizations based on estimates of work performed under the contracts. Expenses for setting up clinical trial sites are accrued immediately. Clinical expenses related to patient enrollment are accrued as patients are enrolled in the trial.

### **Off-Balance Sheet Arrangements**

Since inception, we have not engaged in any off-balance sheet activities.

### **Recent Accounting Pronouncements**

In December 2004 and as amended in April 2005, the FASB issued SFAS No. 123 (revised in 2004), *Share-Based Payment*, or SFAS No. 123R, which replaces SFAS No. 123, *Accounting for Stock-Based Compensation*, and supercedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*. SFAS No. 123R requires all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair value at the beginning of the next fiscal year, with early adoption encouraged. The pro forma disclosures previously permitted under SFAS No. 123 no longer will be an alternative to financial statement recognition. Under SFAS No. 123R, we must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at date of adoption. The transition methods include prospective and retroactive adoption options. Under the retroactive option, prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The prospective method requires that compensation expense be recorded for all unvested stock options and restricted stock at the beginning of the first quarter of adoption of SFAS No. 123R, while the retroactive methods would record compensation expense for all unvested stock options and restricted stock beginning in the first period restated. We are evaluating the requirements of SFAS No. 123R and expect that the adoption of SFAS No. 123R will have a material impact on our results of operations and earnings per share. We have not yet determined the method of adoption or the effect of adopting SFAS No. 123R, and we have not determined whether the adoption will result in amounts that are similar to the current pro forma disclosures under SFAS No. 123.

### **Factors that May Affect our Financial Condition and Results of Operations**

#### **We are a development stage company and we do not have, and may never have, any products.**

We are a development stage medical device company with a limited operating history, and we currently do not have any commercialized products or any source of revenue. We have invested all of our time and resources in developing our continuous glucose monitoring systems, which we initially intend to commercialize in the form of a short-term continuous glucose monitoring system, and subsequently, in the form of a long-term continuous glucose monitoring system. Our existing products under development will require additional clinical evaluation, regulatory approval, significant marketing efforts and substantial additional investment before they can provide us with any revenue. Our efforts may not lead to commercially successful products for a number of reasons, including:

- we may not be able to obtain regulatory approvals for our continuous glucose monitoring systems, or the approved indication for our products may be narrower than we seek;
- our continuous glucose monitoring systems may not prove to be safe and effective in clinical trials;
- we may experience delays in our development program;
- patients may not receive sufficient reimbursement from third-party payors to promote widespread use of our continuous glucose monitoring systems;
- any products that are approved may not be accepted in the marketplace by physicians and patients;
- we may not have adequate financial or other resources to complete the development and commercialization of our continuous glucose monitoring systems or other products;

- we may not be able to manufacture our products in commercial quantities or at an acceptable cost; and
- rapid technological change may make our technology and products obsolete.

We do not expect to be able to commercialize our short-term continuous glucose monitoring system or long-term continuous glucose monitoring system before 2006 and 2007, respectively. If we are unable to develop, obtain regulatory approval for or successfully commercialize our continuous glucose monitoring systems, we will be unable to generate revenue.

**We have incurred losses since inception and anticipate that we will incur continued losses for the foreseeable future.**

We have incurred net losses in each year since our inception in May 1999, including net loss attributable to common stockholders of \$12.5 million for the six months ended June 30, 2005. As of June 30, 2005, we had a deficit accumulated during the development stage of \$65.4 million. We have financed our operations primarily through private placements of our equity securities and our IPO, and have devoted substantially all of our resources to research and development relating to our continuous glucose monitoring systems. We expect our research and development expenses to increase in connection with our clinical trials and other development activities related to our products. If we receive approval for marketing of a product by the Food and Drug Administration, or FDA, we expect to incur significant sales and marketing expenses, and manufacturing expenses. Additionally, we expect that our general and administrative expenses will increase due to the additional operational and regulatory burdens applicable to public companies. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity.

**We have not received, and may never receive, FDA approval to market our continuous glucose monitoring systems.**

We do not have the necessary regulatory approvals to market our continuous glucose monitoring systems or any other product in the United States or in any foreign market. We plan initially to launch our products, once approved, in the United States. The regulatory approval process for our continuous glucose monitoring systems involves, among other things, successfully completing clinical trials and obtaining a premarket approval, or PMA, from the FDA. The PMA process requires us to prove the safety and efficacy of our continuous glucose monitoring systems to the FDA's satisfaction. This process can be expensive and uncertain, requires detailed and comprehensive scientific and human clinical data, generally takes one to three years after a PMA application is filed and may never result in the FDA granting a PMA. For example, there is no guarantee that the PMA application we submitted in March 2005 for our short-term continuous glucose monitoring system will result in any approval of the system by the FDA. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- our systems may not be safe or effective to the FDA's satisfaction;
- the data from our pre-clinical studies and clinical trials may be insufficient to support approval;
- the manufacturing process or facilities we use may not meet applicable requirements; and
- changes in FDA approval policies or adoption of new regulations may require additional data.

In July of 2005, we met with the FDA to discuss the progress of our PMA application. At this meeting we received verbal requests for additional information and were told that the FDA will follow up these verbal requests in writing. While we believe that we can respond expeditiously to this FDA request, there can be no assurance that we can successfully answer all of the FDA's questions in a timely manner, if at all. Any request for additional information by the FDA can potentially extend the timeline to approval.

Even if approved, our continuous glucose monitoring systems may not be approved for the indications that are necessary or desirable for successful commercialization of our systems. We may not obtain the necessary regulatory approvals to market our continuous glucose monitoring systems in the United States or anywhere else. Any delay in, or failure to receive or maintain, approval for our continuous glucose monitoring systems could prevent us from generating revenue or achieving profitability.

**We expect to operate in a highly competitive market, we face competition from large, well-established medical device manufacturers with significant resources, and we may not be able to compete effectively.**

The market for glucose monitoring devices is intensely competitive, subject to rapid change and significantly affected by new product introductions and other market activities of industry participants. If our products are approved for marketing, we will compete directly with Roche Disetronic, a division of Roche Diagnostics; LifeScan, Inc., a division of Johnson & Johnson; the MediSense and TheraSense divisions of Abbott Laboratories; and Bayer Corporation, each of which manufactures and markets products for the single-point finger stick device market. Collectively these companies currently account for substantially all of the glucose monitoring market. Several companies are developing or marketing early generation short-term continuous glucose

monitoring products that will compete directly with our planned products. These devices include the Guardian Continuous Glucose Monitoring System and the CGMS System Gold, both of which have received FDA approval for limited applications and are currently marketed by Medtronic, Inc., and the Freestyle Navigator Glucose System, which has not yet received FDA approval and is being developed by TheraSense. In August 2004, Medtronic announced that it had filed a PMA supplement for its Guardian device that, if approved, will allow it to show real-time glucose measurements to patients. Furthermore, several other companies are developing non-invasive continuous glucose monitoring products. One of these non-invasive devices, the Cygnus GlucoWatch, now owned by Animas Corporation, has received FDA approval. Most of the companies developing or marketing competing devices are publicly traded or divisions of publicly-traded companies, and these companies enjoy several competitive advantages, including:

- significantly greater name recognition;
- established relations with healthcare professionals, customers and third-party payors;
- established distribution networks;
- additional lines of products, and the ability to offer rebates or bundle products to offer higher discounts or incentives to gain a competitive advantage;
- greater experience in conducting research and development, manufacturing, clinical trials, obtaining regulatory approval for products and marketing approved products; and
- greater financial and human resources for product development, sales and marketing, and patent litigation.

As a result, we may not be able to compete effectively against these companies or their products.

**No continuous glucose monitoring system has yet received FDA clearance as a replacement for single-point finger stick devices, and our products may never be approved for that indication.**

We do not expect that our initial products will eliminate the need for single-point finger stick devices. We believe that our initial products, if approved, will be indicated for use by patients to obtain real-time blood glucose levels, trend information and alerts, but not as a substitute for single-point finger stick devices. No precedent for FDA approval of continuous glucose monitoring systems as a substitute for such devices has been established. Accordingly, there is no established study design or agreement regarding performance requirements or measurements in clinical trials for continuous glucose monitoring systems. To our knowledge, the only company to attempt to obtain approval from the FDA for the replacement of single-point finger stick devices with a continuous glucose monitoring system has experienced substantial delays, and there can be no guarantee that we will not also experience such delays.

**If we are unable to successfully complete the pre-clinical studies or clinical trials necessary to support additional PMA applications, our ability to commercialize our continuous glucose monitoring systems and our financial position will be impaired.**

Before submitting any PMA application, we must successfully complete pre-clinical studies and clinical trials that we believe will demonstrate that the product is safe and effective. Product development, including pre-clinical studies and clinical trials, is a long, expensive and uncertain process and is subject to delays and failure at any stage. Furthermore, the data obtained from the trial may be inadequate to support approval of a PMA application. While we obtained an Investigational Device Exemption, or IDE, prior to commencing the current clinical trial for our long-term continuous glucose monitoring system, FDA approval of an IDE application permitting us to conduct testing does not mean that the FDA will consider the data gathered in the trial sufficient to support approval of a PMA application, even if the trial's intended safety and efficacy endpoints are achieved.

The commencement or completion of any of our clinical trials may be delayed or halted, or be inadequate to support approval of a PMA application, for numerous reasons, including, but not limited to, the following:

- the FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold;
- patients do not enroll in clinical trials at the rate we expect;
- patients do not comply with trial protocols;
- patient follow-up is not at the rate we expect;

- patients experience adverse side effects;
- patients die during a clinical trial, even though their death may not be related to our products;
- institutional review boards and third-party clinical investigators may delay or reject our trial protocol;
- third-party clinical investigators decline to participate in a trial or do not perform a trial on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices or other FDA requirements;
- third-party organizations do not perform data collection and analysis in a timely or accurate manner;
- regulatory inspections of our clinical trials or manufacturing facilities may, among other things, require us to undertake corrective action or suspend or terminate our clinical trials;
- changes in governmental regulations or administrative actions;
- the interim or final results of the clinical trial are inconclusive or unfavorable as to safety or efficacy; and
- the FDA concludes that our trial design is inadequate to demonstrate safety and efficacy.

The results of pre-clinical studies do not necessarily predict future clinical trial results, and predecessor clinical trial results may not be repeated in subsequent clinical trials. We believe the data and performance from each of our last three clinical trials relating to our long-term system were likely insufficient to support a PMA application. While these previous trials were not designed or intended to be used to support a PMA application, our ongoing and future clinical trials that are designed to support a PMA application may not be sufficient to do so. Additionally, the FDA may disagree with our interpretation of the data from our pre-clinical studies and clinical trials, or may find the clinical trial design, conduct or results inadequate to prove safety or efficacy, and may require us to pursue additional pre-clinical studies or clinical trials, which could further delay the approval of our products. If we are unable to demonstrate the safety and efficacy of our products in our clinical trials, we will be unable to obtain regulatory approval to market our products. The data we collect from our current clinical trials, our pre-clinical studies and other clinical trials may not be sufficient to support FDA approval. If we are unsuccessful in either filing a PMA application or receiving FDA approval for a PMA application related to our long-term system, our business strategy may have to be altered to rely solely on our short-term system.

**If we are unable to obtain acceptable prices or adequate reimbursement for our products from third-party payors, we will be unable to generate significant revenue.**

The availability of insurance coverage and reimbursement for newly approved medical devices is uncertain. In the United States, patients using existing single-point finger stick devices are generally reimbursed all or part of the product cost by Medicare or other third-party payors. The commercial success of our continuous glucose monitoring systems in both domestic and international markets will be substantially dependent on whether third-party coverage and reimbursement is available for patients that use our systems. Third-party coverage may be particularly difficult to obtain if our systems are not approved by the FDA as replacements for existing single-point finger stick devices. Medicare, Medicaid, health maintenance organizations and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new medical devices, and, as a result, they may not cover or provide adequate payment for our systems. In order to obtain reimbursement arrangements, we may have to agree to a net sales price lower than the net sales price we might charge in other sales channels. The continuing efforts of government and third-party payors to contain or reduce the costs of healthcare may limit our revenue. Our initial dependence on the commercial success of our short-term continuous glucose monitoring system makes us particularly susceptible to any cost containment or reduction efforts. Accordingly, even if our short-term continuous glucose monitoring system or future products we develop are approved for commercial sale, unless government and other third-party payors provide adequate coverage and reimbursement for our products, patients may not use them.

In some foreign markets, pricing and profitability of medical devices are subject to government control. In the United States, we expect that there will continue to be federal and state proposals for similar controls. Also, the trends toward managed healthcare in the United States and proposed legislation intended to reduce the cost of government insurance programs could significantly influence the purchase of healthcare services and products and may result in lower prices for our products or the exclusion of our products from reimbursement programs.

**Our continuous glucose monitoring systems may never achieve market acceptance even if we obtain regulatory approvals.**

To date, only those patients and physicians involved in our clinical trials have used our products and, even if we obtain regulatory approval, people with diabetes or the medical community may not endorse our short-term or long-term continuous glucose monitoring systems. The degree of market acceptance of our products will depend on a number of factors, including:

- perceived effectiveness of the systems;
- convenience of use;
- cost of our continuous glucose monitoring systems;
- adequacy of third-party coverage or reimbursement;
- approved indications and product labeling;
- publicity concerning our products or competitive products;
- prevalence and severity of any side effects;
- potential advantages over alternative glucose monitoring methods;
- introduction and acceptance of competing products or technologies; and
- extent and success of our sales, marketing and distribution efforts.

Our products, and in particular our long-term continuous glucose monitoring system, can be more invasive than current self-monitored glucose testing systems, including single-point finger stick devices, and patients may be unwilling to insert or implant a sensor in their body, especially if their current diabetes management involves no more than two finger sticks per day. Moreover, patients may not perceive the benefits of continuous glucose monitoring and may be unwilling to change their current treatment regimens. In addition, physicians tend to be slow to change their medical treatment practices because of perceived liability risks arising from the use of new products and the uncertainty of third party reimbursement. Physicians may not recommend or prescribe our products until there is long-term clinical evidence to convince them to alter their existing treatment methods and there are recommendations from prominent physicians that our products are effective in monitoring blood glucose levels. We cannot predict when, if ever, physicians may adopt the use of our products. If our continuous glucose monitoring systems are approved but do not achieve an adequate level of acceptance by patients, physicians and healthcare payors, we may not generate significant product revenue and we may not become profitable.

**We depend on clinical investigators and clinical sites to enroll patients in our clinical trials and other third parties to manage the trials and to perform related data collection and analysis, and, as a result, we may face costs and delays that are outside of our control.**

We rely on clinical investigators and clinical sites to enroll patients in our clinical trials and other third parties to manage the trial and to perform related data collection and analysis. However, we may not be able to control the amount and timing of resources that clinical sites may devote to our clinical trials. If these clinical investigators and clinical sites fail to enroll a sufficient number of patients in our clinical trials or fail to ensure compliance by patients with clinical protocols, we will be unable to complete these trials, which could prevent us from obtaining regulatory approvals for our products. Our agreements with clinical investigators and clinical sites for clinical testing place substantial responsibilities on these parties and, if these parties fail to perform as expected, our trials could be delayed or terminated. If these clinical investigators, clinical sites or other third parties do not carry out their contractual duties or obligations or fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, our clinical trials may be extended, delayed or terminated, and we may be unable to obtain regulatory approval for, or successfully commercialize, our products.

**We may be unable to complete the development and commercialization of our continuous glucose monitoring systems or other products without additional funding.**

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts on research and development, including conducting clinical trials for our continuous glucose monitoring systems. Even before we receive approval to market one of our continuous glucose monitoring systems, we expect to spend significant additional amounts on commercializing the product, including development of a direct sales force and expansion of manufacturing capacity. For the six months ended June 30, 2005, our net cash used in operating activities was \$10.3 million, compared to \$5.3 million for the same period in 2004. We expect that our cash used by operations will increase significantly in each of the next several years, and

we may need additional funds to complete the development and commercialization of both our short-term and long-term continuous glucose monitoring systems. Additional financing may not be available on a timely basis on terms acceptable to us, or at all. Any additional financing may be dilutive to stockholders or may require us to grant a lender a security interest in our assets. The amount of funding we will need will depend on many factors, including:

- the rate of progress and cost of our clinical trials and other development activities;
- the success of our research and development efforts;
- the costs and timing of regulatory approval;
- the expenses we incur in developing, selling and marketing our products;
- the revenue generated by sales of our future products;
- the emergence of competing or complementary technological developments;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual product rights;
- the terms and timing of any collaborative, licensing or other arrangements that we may establish; and
- the acquisition of businesses, products and technologies, although we currently have no commitments or agreements relating to any of these types of transactions.

If adequate funds are not available, we may have to delay development or commercialization of our products or license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize. We also may have to reduce marketing, customer support or other resources devoted to our products. Any of these factors could harm our financial condition.

**If we are unable to establish sales, marketing and distribution capabilities or enter into and maintain arrangements with third parties to sell, market and distribute our continuous glucose monitoring systems, our business may be harmed.**

We do not have a sales organization and have no experience as a company in the sale, marketing and distribution of glucose monitoring products. To achieve commercial success for any approved product we must either develop a sales and marketing force or enter into arrangements with others to market and sell our products. Following product approval, we currently plan to establish a small direct sales force to market our products in the United States. Our sales force will be competing with the experienced and well-funded marketing and sales operations of our competitors. Developing a sales force is expensive and time consuming and could delay or limit the success of any product launch. We may not be able to develop this capacity on a timely basis or at all. If we are unable to establish sales and marketing capabilities, we will need to contract with third parties to market and sell our approved products in the United States. To the extent that we enter into arrangements with third parties to perform sales, marketing and distribution services in the United States, our product revenue could be lower than if we directly marketed and sold our continuous glucose monitoring systems. Furthermore, to the extent that we enter into co-promotion or other marketing and sales arrangements with other companies, any revenue received will depend on the skills and efforts of others, and we do not know whether these efforts will be successful. If we are unable to establish and maintain adequate sales, marketing and distribution capabilities, independently or with others, we may not be able to generate product revenue and may not become profitable.

**We have limited manufacturing capabilities and manufacturing personnel, and if our manufacturing capabilities are insufficient to produce an adequate supply of products, our growth could be limited and our business could be harmed.**

We currently have limited resources, facilities and experience to commercially manufacture our products. In order to produce our continuous glucose monitoring systems in the quantities we anticipate to meet market demand, we will need to increase our manufacturing capacity by a significant factor over the current level. There are technical challenges to increasing manufacturing capacity, including equipment design and automation, material procurement, problems with production yields, and quality control and assurance. Developing commercial-scale manufacturing facilities will require the investment of substantial additional funds and the hiring and retaining of additional management and technical personnel who have the necessary manufacturing experience. Also, the scaling of manufacturing capacity is subject to numerous risks and uncertainties, such as the availability and suitability of facility space, construction timelines, design, installation and maintenance of manufacturing equipment, among others, which can lead to unexpected delays. Even if our products receive regulatory approval, if we are unable to manufacture a sufficient supply of product, maintain control over expenses or otherwise adapt to anticipated growth, or if we underestimate growth, we may not have the capability to satisfy market demand and our business will suffer.

Additionally, the production of our continuous glucose monitoring systems must occur in a highly controlled and clean environment to minimize particles and other yield- and quality-limiting contaminants. Weaknesses in process control or minute impurities in materials may cause a substantial percentage of defective products in a lot. If we are not able to maintain stringent quality controls, or if contamination problems arise, our clinical development and commercialization efforts could be delayed, which would harm our business and our results of operations.

**Our manufacturing operations are dependent upon third-party suppliers, making us vulnerable to supply problems and price fluctuations, which could harm our business.**

We rely on Flextronics to manufacture and supply the handheld personal receiver included as part of our continuous glucose monitoring systems and the circuit boards for our short-term and long-term sensors; we rely on AMI Semiconductor to manufacture and supply the application specific integrated circuit, or ASIC, that is incorporated into the transmitter for our continuous glucose monitoring systems; we rely on Quallion to manufacture and supply the battery included in our short-term sensor and the third generation of our long-term sensor; and we rely on Vita Needle to manufacture and supply the insertion needle in our short-term continuous glucose monitoring system. Each of these suppliers is a sole-source supplier. Generally, our agreements with these and our other suppliers can be terminated by either party upon short notice. Our contract manufacturers also rely on sole-source suppliers to manufacture some of the components used in our products. Our manufacturers and suppliers may encounter problems during manufacturing due to a variety of reasons, including failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunction and environmental factors, any of which could delay or impede their ability to meet our demand. Our reliance on these outside manufacturers and suppliers also subjects us to other risks that could harm our business, including:

- suppliers may make errors in manufacturing components that could negatively affect the efficacy or safety of our products or cause delays in shipment of our products;
- we may not be able to obtain adequate supply in a timely manner or on commercially reasonable terms;
- we may have difficulty locating and qualifying alternative suppliers for our sole-source supplies;
- switching components may require product redesign and submission to the FDA of a PMA supplement or possibly a separate PMA, either of which could significantly delay production;
- our suppliers manufacture products for a range of customers, and fluctuations in demand for the products these suppliers manufacture for others may affect their ability to deliver components to us in a timely manner; and
- our suppliers may encounter financial hardships unrelated to our demand for components, which could inhibit their ability to fulfill our orders and meet our requirements.

We may not be able to quickly establish additional or replacement suppliers, particularly for our single-source components and especially after our products are commercialized, in part because of the FDA approval process and because of the custom nature of various parts we design. Any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and cause them to cancel orders or switch to competitive products.

**Technological breakthroughs in the glucose monitoring market could render our products obsolete.**

The glucose monitoring market is subject to rapid technological change and product innovation. Our products are based on our proprietary technology, but a number of companies and medical researchers are pursuing new technologies for the monitoring of glucose levels. FDA approval of a commercially viable continuous glucose monitor or sensor produced by one of our competitors could significantly reduce market acceptance of our systems. Several of our competitors are in various stages of developing continuous glucose monitors or sensors, including non-invasive and invasive devices, and the FDA has approved three of these products. In addition, the National Institutes of Health and other supporters of diabetes research are continually seeking ways to prevent, cure or improve treatment of diabetes. Therefore, our products may be rendered obsolete by technological breakthroughs in diabetes monitoring, treatment or prevention.

**Potential long-term complications from our continuous glucose monitoring systems may not be revealed by our clinical experience to date.**

If unanticipated long-term side-effects result from the use of either of our systems, we could be subject to liability and our systems would not be widely adopted. Our clinical trials have been limited to seven months of continuous use with our first generation long-term sensor, six months of continuous use with our second generation long-term sensor and seven days of continuous use with our short-term sensor. Additionally, we have not clinically tested repeated use of our long-term sensor in the

same patient, and we have limited clinical experience with repeated use of our short-term sensor in the same patient. We cannot assure you that long-term use would not result in unanticipated complications. Furthermore, the interim results from our current pre-clinical studies and clinical trials may not be indicative of the clinical results obtained when we examine the patients at later dates. It is possible that repeated use of our short-term or long-term systems, or implantation of our long-term sensor for more than seven months, will result in unanticipated adverse effects, potentially even after the device is removed.

**Even if our products are approved by regulatory authorities, if we or our suppliers fail to comply with ongoing regulatory requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.**

Any product for which we obtain marketing approval, along with the manufacturing processes, post-approval clinical data and promotional activities for such product, will be subject to continual review and periodic inspections by the FDA and other regulatory bodies. In particular we and our suppliers are required to comply with the quality system regulation, or QSR, and other regulations, which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of our products. The FDA enforces the QSR through unannounced inspections. We have not yet successfully completed such an inspection and will be required to before we ship any commercial products. Failure by us or one of our suppliers to comply with statutes and regulations administered by the FDA and other regulatory bodies, or failure to take adequate response to any observations, could result in, among other things, any of the following actions:

- warning letters;
- fines and civil penalties;
- unanticipated expenditures;
- delays in approving or refusal to approve our continuous glucose monitoring systems;
- withdrawal of approval by the FDA or other regulatory bodies;
- product recall or seizure;
- interruption of production;
- operating restrictions;
- injunctions; and
- criminal prosecution.

If any of these actions were to occur, it would harm our reputation and cause our product sales and profitability to suffer. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with applicable regulatory requirements.

Even if regulatory approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as the QSR, may result in restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties.

**We face the risk of product liability claims and may not be able to maintain or obtain insurance.**

Our business exposes us to the risk of product liability claims that is inherent in the testing, manufacturing and marketing of medical devices, including those which may arise from the misuse or malfunction of, or design flaws in, our products. We may be subject to product liability claims if our products cause, or merely appear to have caused, an injury. Claims may be made by patients, healthcare providers or others selling our products. Although we have product liability and clinical trial liability insurance that we believe is appropriate, this insurance is subject to deductibles and coverage limitations. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, the coverages may not be adequate to protect us against any future product liability claims. In addition, if any of our products are approved for marketing, we may seek additional insurance coverage. If we are unable to obtain insurance at an acceptable cost or on acceptable terms with

adequate coverage or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may harm our business. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could result in significant costs and significant harm to our business.

We may be subject to claims against us even if the apparent injury is due to the actions of others. For example, we rely on the expertise of physicians, nurses and other associated medical personnel to perform the medical procedure and related processes to implant our long-term sensor into patients. If these medical personnel are not properly trained or are negligent, the capabilities of our products may be diminished or the patient may suffer critical injury, which may subject us to liability. These liabilities could prevent or interfere with our product commercialization efforts. Defending a suit, regardless of merit, could be costly, could divert management attention and might result in adverse publicity, which could result in the withdrawal of, or inability to recruit, clinical trial volunteers or result in reduced acceptance of our products in the market.

**We conduct business in a heavily regulated industry and if we fail to comply with these laws and government regulations, we could suffer penalties or be required to make significant changes to our operations.**

The healthcare industry is subject to extensive federal, state and local laws and regulations relating to:

- billing for services;
- financial relationships with physicians and other referral sources;
- inducements and courtesies given to patients;
- quality of medical equipment and services;
- confidentiality, maintenance and security issues associated with medical records and individually identifiable health information;
- medical device reporting;
- false claims;
- professional licensure; and
- labeling products.

These laws and regulations are extremely complex and, in some cases, still evolving. In many instances, the industry does not have the benefit of significant regulatory or judicial interpretation of these laws and regulations. If our operations are found to be in violation of any of the federal, state or local laws and regulations which govern our activities, we may be subject to the applicable penalty associated with the violation, including civil and criminal penalties, damages, fines or curtailment of our operations. The risk of being found in violation of these laws and regulations is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's time and attention from the operation of our business.

In addition, healthcare laws and regulations may change significantly in the future. Any new healthcare laws or regulations may adversely affect our business. A review of our business by courts or regulatory authorities may result in a determination that could adversely affect our operations. Also, the healthcare regulatory environment may change in a way that restricts our operations.

We are not aware of any governmental healthcare investigations involving our executives or us. However, any future healthcare investigations of our executives, our managers or us could result in significant liabilities or penalties to us, as well as adverse publicity.

**Our inability to adequately protect our intellectual property could allow our competitors and others to produce products based on our technology, which could substantially impair our ability to compete.**

Our success and ability to compete is dependent, in part, upon our ability to maintain the proprietary nature of our technologies. We rely on a combination of patent, copyright and trademark law, and trade secrets and nondisclosure agreements to protect our intellectual property. However, such methods may not be adequate to protect us or permit us to gain or maintain a competitive advantage. Our patent applications may not issue as patents in a form that will be advantageous to us, or at all. Our issued patents, and those that may issue in the future, may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products.

To protect our proprietary rights, we may in the future need to assert claims of infringement against third parties to protect our intellectual property. The outcome of litigation to enforce our intellectual property rights in patents, copyrights, trade secrets or trademarks is highly unpredictable, could result in substantial costs and diversion of resources, and could have a material adverse effect on our financial condition and results of operations regardless of the final outcome of such litigation. In the event of an adverse judgment, a court could hold that some or all of our asserted intellectual property rights are not infringed, invalid or unenforceable, and could award attorney fees.

Despite our efforts to safeguard our unpatented and unregistered intellectual property rights, we may not be successful in doing so or the steps taken by us in this regard may not be adequate to detect or deter misappropriation of our technology or to prevent an unauthorized third party from copying or otherwise obtaining and using our products, technology or other information that we regard as proprietary. Additionally, third parties may be able to design around our patents. Furthermore, the laws of foreign countries may not protect our proprietary rights to the same extent as the laws of the United States. Our inability to adequately protect our intellectual property could allow our competitors and others to produce products based on our technology, which could substantially impair our ability to compete.

We do not currently have any registered trademarks. We recently filed for the registration of a trademark for the name "DexCom" but our application has been rejected. We have appealed this rejection. The examining attorney has withdrawn the refusal and has approved the mark for publication for opposition. If we cannot obtain a trademark registration for DexCom, we may have to change our company name or market our products under a different name, which could result in significant expense.

**We may become subject to claims of infringement or misappropriation of the intellectual property rights of others, which could prohibit us from shipping affected products, require us to obtain licenses from third parties or to develop non-infringing alternatives, and subject us to substantial monetary damages and injunctive relief.**

Third parties could, in the future, assert infringement or misappropriation claims against us with respect to our current or future products. Whether a product infringes a patent involves complex legal and factual issues, the determination of which is often uncertain. Therefore, we cannot be certain that we have not infringed the intellectual property rights of such third parties or others. Our competitors may assert that our continuous glucose monitoring systems or the methods we employ in the use of our systems are covered by U.S. or foreign patents held by them. This risk is exacerbated by the fact that there are numerous issued patents and pending patent applications relating to self-monitored glucose testing systems and implantable sensors in the medical technology field. Because patent applications may take years to issue, there may be applications now pending of which we are unaware that may later result in issued patents that our products infringe. There could also be existing patents of which we are unaware that one or more components of our system may inadvertently infringe. As the number of competitors in the market for self-monitored glucose testing systems grows, the possibility of inadvertent patent infringement by us or a patent infringement claim against us increases.

Any infringement or misappropriation claim could cause us to incur significant costs, could place significant strain on our financial resources, divert management's attention from our business and harm our reputation. If the relevant patents were upheld as valid and enforceable and we were found to infringe, we could be prohibited from selling our product that is found to infringe unless we could obtain licenses to use the technology covered by the patent or are able to design around the patent. We may be unable to obtain a license on terms acceptable to us, if at all, and we may not be able to redesign our products to avoid infringement. A court could also order us to pay compensatory damages for such infringement, plus prejudgment interest and could, in addition, treble the compensatory damages and award attorney fees. These damages could be substantial and could harm our reputation, business, financial condition and operating results. A court also could enter orders that temporarily, preliminarily or permanently enjoin us and our customers from making, using, selling, offering to sell or importing our products, or could enter an order mandating that we undertake certain remedial activities. Depending on the nature of the relief ordered by the court, we could become liable for additional damages to third parties.

**The prosecution and enforcement of patents licensed to us by third parties are not within our control, and without these technologies, our products may not be successful and our business would be harmed.**

We rely on a license from SM Technologies, LLC to use various technologies that are material to our business. We do not own the patents that underlie this license. This license grants us exclusive rights under specific patents related to our biointerface membranes and our sensor membranes and allows us to use those rights only in the field of diabetes treatment and management. Our rights to use these technologies and employ the inventions claimed in the licensed patents are subject to our abiding by the terms of the license. In addition, we do not control the prosecution of the patents subject to this license or the strategy for determining when such patents should be enforced. As a result, we are largely dependent upon our licensor to determine the appropriate strategy for prosecuting and enforcing those patents.

**We do not currently comply with Federal Communications Commission, or FCC, regulations for the radio transmissions used by our products, and will need to change the frequencies we use, or obtain exemptions for our systems, before we can commercialize our products.**

Our continuous glucose monitoring systems rely on radio transmissions from the sensor to a handheld receiver. Our continuous glucose monitoring systems operate in the band of frequencies allocated to the Medical Implant Communications Service, or MICS, which is an ultra-low power, unlicensed, mobile radio service for transmitting data in support of diagnostic or therapeutic functions associated with implanted medical devices. However, our continuous glucose monitoring system does not fully comply with the requirements imposed by the FCC on MICS devices. We applied for permanent exemption from certain MICS requirements in May of 2005. In July of 2005 during a public comment period, Medtronic filed a comment in opposition to our waiver request. Biotronic, the Juvenile Diabetes Research Foundation, or JDRF, and others have written the FCC in support of our waiver. We may not obtain such an exemption in time for our potential product release, if at all. If we cannot obtain an exemption, we may be required to re-engineer our sensors to transmit over a different frequency that is not restricted. Any change to our transmission frequency may require changes to our regulatory approvals. We have not tested, in a clinical setting, any of our current generation systems on a frequency other than that allocated to the MICS. While other frequencies are available, traffic on those frequencies may be significant given the lack of restrictions, and we cannot predict the effect such traffic would have on the operation of our sensors.

**All of our operations are conducted at a single location. Any disruption at our facility could increase our expenses.**

All of our operations are conducted at a single location in San Diego, California. We take precautions to safeguard our facility, including insurance, health and safety protocols, and off-site storage of computer data. However, a natural disaster, such as a fire, flood or earthquake, could cause substantial delays in our operations, damage or destroy our manufacturing equipment or inventory, and cause us to incur additional expenses. The insurance we maintain against fires, floods, earthquakes and other natural disasters may not be adequate to cover our losses in any particular case.

**We may be liable for contamination or other harm caused by materials that we handle, and changes in environmental regulations could cause us to incur additional expense.**

Our research and development and clinical processes involve the handling of potentially harmful biological materials as well as hazardous materials. We are subject to federal, state and local laws and regulations governing the use, handling, storage and disposal of hazardous and biological materials and we incur expenses relating to compliance with these laws and regulations. If violations of environmental, health and safety laws occur, we could be held liable for damages, penalties and costs of remedial actions. These expenses or this liability could have a significant negative impact on our financial condition. We may violate environmental, health and safety laws in the future as a result of human error, equipment failure or other causes. Environmental laws could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We are subject to potentially conflicting and changing regulatory agendas of political, business and environmental groups. Changes to or restrictions on permitting requirements or processes, hazardous or biological material storage or handling might require an unplanned capital investment or relocation. Failure to comply with new or existing laws or regulations could harm our business, financial condition and results of operations.

**Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing our products abroad.**

Following commercial launch of our products in the United States, we may market our products internationally. Outside the United States, we can market a product only if we receive a marketing authorization and, in some cases, pricing approval, from the appropriate regulatory authorities. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval in addition to other risks. We may not obtain foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. We have not taken any actions to obtain foreign regulatory approvals. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market on a timely basis, or at all.

**Our success will depend on our ability to attract and retain our personnel.**

We are highly dependent on our senior management, especially Andrew P. Rasdal, our President and Chief Executive Officer, and each of Andrew K. Balo, our Vice President of Clinical and Regulatory Affairs and Quality Systems, Mark Brister, our Vice President, Advanced Development Teams, James H. Brauker, our Vice President of Research and Development, and Steven J. Kemper, our Chief Financial Officer. Our success will depend on our ability to retain our current management and to attract and retain qualified personnel in the future, including scientists, clinicians, engineers and other highly skilled personnel. Competition for senior management personnel, as well as scientists, clinicians and engineers, is intense and we may not be able to retain our

personnel. The loss of the services of members of our senior management, scientists, clinicians or engineers could prevent the implementation and completion of our objectives, including the development and introduction of our products. The loss of a member of our senior management or our professional staff would require the remaining executive officers to divert immediate and substantial attention to seeking a replacement. Each of our officers may terminate their employment at any time without notice and without cause or good reason.

We expect to rapidly expand our operations and grow our research and development, product development and administrative operations. This expansion is expected to place a significant strain on our management and will require hiring a significant number of qualified personnel. Accordingly, recruiting and retaining such personnel in the future will be critical to our success. There is intense competition from other companies and research and academic institutions for qualified personnel in the areas of our activities. If we fail to identify, attract, retain and motivate these highly skilled personnel, we may be unable to continue our development and commercialization activities.

**We will incur increased costs as a result of recently enacted and proposed changes in laws and regulations relating to corporate governance matters.**

Recently enacted and proposed changes in the laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002 and rules adopted or proposed by the Securities and Exchange Commission, or SEC, will result in increased costs to us as we evaluate the implications of any new rules and regulations and respond to new requirements under such rules and regulations. We will be required to comply with these rules and regulations after the completion of this offering. For example, we are evaluating our internal controls systems in order to allow us to report on, and our independent registered public accounting firm to attest to, our internal controls, as required by Section 404 of the Sarbanes-Oxley Act. While we anticipate being able to fully implement the requirements relating to internal controls and all other aspects of Section 404 in a timely fashion, we cannot be certain as to the timing of completion of our evaluation, testing and remediation actions or the impact of the same on our operations since there is no precedent available by which to measure compliance adequacy. As a development stage company with limited capital and human resources, we will need to divert management's time and attention away from our business in order to ensure compliance with these regulatory requirements. This diversion of management's time and attention may have a material adverse effect on our business, financial condition and results of operations.

**Changes in or interpretations of accounting rules and regulations, such as expensing of stock options, could result in unfavorable accounting charges or require us to change our compensation policies.**

Accounting methods and policies for business and market practices, including policies regarding expensing stock options, are subject to further review, interpretation and guidance from relevant accounting authorities, including the SEC. For example, we currently are not required to record stock-based compensation charges if the employee's stock option exercise price equals or exceeds the fair value of our common stock at the date of grant. In December 2004 and as amended in April 2005, the Financial Accounting Standards Board, or FASB, issued SFAS No. 123 (revised 2004), *Share-Based Payment* which will require all share-based payments to employees, including grants of employee stock options, to be recognized in the financial statements based on their fair values at the beginning of the next fiscal year, with early adoption encouraged. The transition methods include retroactive and prospective adoption options. Under the retroactive option, prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The prospective method requires that compensation expense be recorded for all unvested stock options and restricted stock at the beginning of the first quarter of adoption of SFAS No. 123R, while the retroactive methods would record compensation expense for all unvested stock options and restricted stock beginning in the first period restated. If we elect to adopt the retroactive provisions and to restate all prior periods presented our operating expenses and reported losses will increase. We rely heavily on stock options to compensate existing employees and attract new employees. Upon the adoption, we may choose to reduce our reliance on stock options as a compensation tool. If we reduce our use of stock options, it may be more difficult for us to attract and retain qualified employees. Although we believe that our accounting practices are consistent with current accounting pronouncements, changes to or interpretations of accounting methods or policies in the future may require us to reclassify, restate or otherwise change or revise our financial statements.

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

The primary objective of our investment activities is to preserve our capital for the purpose of funding operations while at the same time maximizing the income we receive from our investments without significantly increasing risk. To achieve these objectives, our investment policy allows us to maintain a portfolio of cash equivalents and short-term investments in a variety of securities, including money market funds and corporate debt securities. Due to the short-term nature of our investments, we believe that we have no material exposure to interest rate risk.

To date we have recorded no product sales and have not entered into any agreements denominated in other than U.S. dollars. Accordingly we believe we have no material exposure to risk from changes in foreign currency exchange rates.

**ITEM 4. CONTROLS AND PROCEDURES****Evaluation of Disclosure Controls and Procedures**

Regulations under the Securities Exchange Act of 1934 require public companies to maintain “disclosure controls and procedures,” which are defined to mean a company’s controls and other procedures that are designed to ensure that information required to be disclosed in the reports that it files or submits under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission’s rules and forms. DexCom’s management, including our Chief Executive Officer and our Chief Financial Officer, conducted an evaluation as of the end of the period covered by this report of the effectiveness of our disclosure controls and procedures. Based on their evaluation, our Chief Executive officer and our Chief Financial Officer concluded that our disclosure controls and procedures were effective for this purpose.

**Changes in Internal Control Over Financial Reporting**

There were no changes in our internal control over the financial reporting during our last fiscal quarter that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

**Limitation on Effectiveness of Controls**

It should be noted that any system of controls, however well designed and operated, can provide only reasonable, and not absolute, assurance that the objectives of the system are met. The design of any control system is based, in part, upon the benefits of the control system relative to its costs. Control systems can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. In addition, over time, controls may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of these and other inherent limitations of control systems, there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions, regardless of how remote.

**PART II OTHER INFORMATION****ITEM 1. LEGAL PROCEEDINGS**

Not applicable

**ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS****Unregistered Sales of Equity Securities**

Not applicable

**Use of Proceeds**

Our first Registration Statement on Form S-1 (Reg. No. 333-122454), as amended, became effective April 13, 2005, and the offering commenced the same day. The offering terminated subsequent to the sale of 4,700,000 shares of common stock and the underwriters' overallotment option was not exercised. Piper Jaffray & Co. acted as book-running manager for the offering and, together with SG Cowen & Co., LLC, William Blair & Company, L.L.C. and First Albany Capital Inc., acted as representative of the underwriters.

We registered 4,700,000 shares of common stock at \$0.001 par value per share, plus 705,000 additional shares to cover the underwriters' overallotment option. All shares were registered for our account. The aggregate public offering price of the 4,700,000 shares sold was \$56,400,000.

Expenses incurred in connection with the issuance and distribution of the securities registered were as follows:

- Underwriting discounts and commissions - \$3,948,000
- Other expenses - \$1,973,000
- Total expenses - \$5,921,000

None of such payments were direct or indirect payments to directors or officers of the issuer or their associates or to persons owning 10 percent or more of any class of equity securities of the issuer or any of its affiliates or direct or indirect payments to others. The net offering proceeds to us after deducting underwriters' discounts and the total expenses described above totals approximately \$50.5 million.

Of the net proceeds from the offering and existing cash, we expect to use approximately:

- \$30.0 million for clinical trials and other research and development expenses;
- \$15.0 million for building our commercial infrastructure, including sales and marketing and manufacturing capacity expansion; and
- the remainder for working capital and general corporate purposes.

The amounts actually spent for these purposes may vary significantly and will depend on a number of factors, including our operating costs, capital expenditures and other factors described under "Risk Factors" above. While we have no present understandings, commitments or agreements to enter into any potential acquisitions, we may also use a portion of the net proceeds for the acquisition of, or investment in, technologies or products that complement our business. Accordingly, management will retain broad discretion as to the allocation of the net proceeds of this offering. As required by SEC regulations, we will provide further detail on our use of proceeds from the offering in future periodic reports.

Pending the uses described above, we have invested the net proceeds of the offering in short-term, interest-bearing, investment-grade securities. We cannot predict whether the proceeds will yield a favorable return.

**ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS**

Not applicable

**ITEM 5. OTHER INFORMATION**

Not applicable

**ITEM 6. EXHIBITS**

The following exhibits are filed as a part of this report:

Exhibit Number	Exhibit Description	Incorporated by Reference			Exhibit Number	Provided Herewith
		Form	File No.	Date of First Filing		
10.12	Lease from Hub Properties Trust, to DexCom, Inc. dated May 13, 2005.	8-K	N/A	May 18, 2005	10.12	—
31.01	Certification of Chief Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(a).	—	—	—	—	X
31.02	Certification of Chief Financial Officer Pursuant to Securities Exchange Act Rule 13a-14(a).	—	—	—	—	X
32.01	Certification of Chief Executive Officer Pursuant to 18 U.S.C. Section 1350 and Securities Exchange Act Rule 13a-14(b).*	—	—	—	—	X
32.02	Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350 and Securities Exchange Act Rule 13a-14(b).*	—	—	—	—	X

\* This certification is not deemed "filed" for purposes of Section 18 of the Securities Exchange Act, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent that DexCom specifically incorporates it by reference.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

DEXCOM, INC.  
(Registrant)

Dated: August 2, 2005

By: /s/ Andrew P. Rasdal

**Andrew P. Rasdal,  
President and Chief Executive Officer**

Dated: August 2, 2005

By: /s/ Steven J. Kemper

**Steven J. Kemper,  
Chief Financial Officer**

29

**Exhibit 31.01**

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Andrew P. Rasdal, certify that:

1. I have reviewed this quarterly report on Form 10-Q of DexCom, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including any consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 2, 2005

By: /s/ Andrew P. Rasdal  
Andrew P. Rasdal  
*President and Chief Executive Officer*

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Steven J. Kemper, certify that:

1. I have reviewed this quarterly report on Form 10-Q of DexCom, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including any consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - c) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 2, 2005

By: /s/ Steven J. Kemper  
Steven J. Kemper  
*Chief Financial Officer*

**Exhibit 32.01**

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER  
PURSUANT TO  
18 U.S.C SECTION 1350**

The undersigned, Andrew P. Rasdal, the President and Chief Executive Officer of DexCom, Inc. (the "Company"), pursuant to 18 U.S.C. §1350, hereby certifies that:

- (i) the Quarterly Report on Form 10-Q for the period ended June 30, 2005 of the Company (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934.
- (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 2, 2005

/s/ Andrew P. Rasdal.  
Andrew P. Rasdal  
President and Chief Executive Officer

CERTIFICATION OF CHIEF FINANCIAL OFFICER  
PURSUANT TO  
18 U.S.C. SECTION 1350

The undersigned, Steven J. Kemper, Chief Financial Officer, of DexCom, Inc. (the "Company"), pursuant to 18 U.S.C. §1350, hereby certifies:

- (i) the Quarterly Report on Form 10-Q for the period ended June 30, 2005 of the Company (the "Report") fully complies with the requirements of Section 13(a) and 15(d) of the Securities Exchange Act of 1934; and
- (ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: August 2, 2005

/s/ Steven J. Kemper  
Steven J. Kemper  
Chief Financial Officer

---

**End of Filing**

Powered By **EDGAR®**  
Online®

© 2005 | EDGAR Online, Inc.